



BILLING CODE: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-16-16JD; Docket No. CDC-2016-0004]

**Proposed Data Collection Submitted for Public Comment and
Recommendations**

AGENCY: Centers for Disease Control and Prevention (CDC),
Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on the proposed information collection entitled "Young Men who have Sex with Men (YMSM) Study Thailand". CDC is requesting a three-year approval for this new project.

DATES: Written comments must be received on or before **[INSERT
DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2016-0004 by any of the following methods:

- Federal eRulemaking Portal: Regulation.gov. Follow the instructions for submitting comments.
- Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to Regulations.gov, including any personal information provided. For access to the docket to read background documents or comments received, go to Regulations.gov.

Please note: All public comment should be submitted through the Federal eRulemaking portal (Regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation,

maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

Cohort Study of HIV, STIs and Preventive Interventions among Young MSM in Thailand - New - National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

This is a new information collection request for 3 years of data collection.

In Thailand, there is a very high HIV incidence in men who have sex with men (MSM) and transgender women (TGW). It is estimated that over 50% of all new HIV infections are occurring in MSM and TGW. At Silom Community Clinic @Tropical Medicine (SCC @TropMed), there is a reported average HIV prevalence of 28% and HIV incidence of 8 per 100 person-years in young men.

An area with gaps of understanding regarding the HIV epidemic in Thailand, as well as globally, is the epidemiology, risk factors, and HIV beliefs and knowledge of gay identified and transgender youth. In 2013, UNAIDS reported that 95% of new HIV infections were in low- and middle-income countries, where more than one third were in young people (<18 years) who were unaware of their HIV status. Adolescents living with HIV are more likely to die from AIDS, and there is little tracking of the HIV epidemic and outcomes in adolescents.

We propose a study of males aged 15-29 years at risk for HIV. The SCC @TropMed, the clinical site of the activity, is a Clinical Research Site (CRS) and that conducts HIV prevention research in network clinical trials supported by National Institute of Health (NIH). The data will be collected from young MSM and TGW in Bangkok, Thailand through the CRS that serves MSM and transgender women (TGW). Although there are other MSM and TGW clinic settings in Bangkok, there is no cohort data providing information on incidence and risk factors for HIV

incidence in the young. Therefore, this study also includes a longitudinal assessment (cohort) to assess HIV and sexually transmitted infection incidence and prevalence. This study also includes a qualitative component to assess adolescent and key leaders HIV prevention knowledge and practices. A study of young men at risk in Thailand is urgently needed to provide needed data to assess and implement prevention strategies and inform policies for HIV prevention in Thailand, as well as globally. There is no cost to participants other than their time.

The total estimated annualized burden hours are 814.

Estimated Annualized Burden Hours

Type of respondent	Form Name	No. of Respondents	No. Responses	Average Burden per Response (in hours)	Total Burden Hours
Community members	FGD Consent Assent	10	1	30/60	5
Community members	FGD	10	1	2	20
Community members	KII Consent Assent	4	1	30/60	2
Community members	KII	4	1	2	8
Community members	Screening checklist	300	1	15/60	75
Potential Participant	Screening Consent Assent	300	1	30/60	150
Potential Participant	Screening CASI	300	1	15/60	75
HIV-positive	HIV CASI	60	1	2/60	2

at screening					
Participants	Enrollment Consent Assent	167	1	30/60	84
Participants	Follow-up CASI	167	4	15/60	167
Participants	YMSM Clinical Form	167	4	20/60	223
HIV-positive Participants	HIV CASI Cohort	46	4	1 /60	3
Total					814

Leroy A. Richardson,

*Chief, Information Collection Review Office,
Office of Scientific Integrity,
Office of the Associate Director for Science,
Office of the Director,
Centers for Disease Control and Prevention.*

[FR Doc. 2016-564 Filed: 1/13/2016 8:45 am; Publication Date: 1/14/2016]